

changes to the specification to address these objections. The Examiner requested that the trademark PHOTOLINK® be accompanied by the generic terminology and that “any errors of which applicant may become aware in the specification” be corrected. Applicants submit that the trademark PHOTOLINK® is already accompanied by the generic terminology (page 13, lines 27-30) and that applicants are not aware of any errors in the specification.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 1-4, 13-19, 21 and 23-26 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ekins et al. (EP 304,202). This rejection is respectfully traversed.

The present invention relates to a microscale binding assay, an analyte binding array and a kit for use in a binding assay. Claim 1 is directed to a binding assay and requires “the analyte binding partner in the sorbent zone being present in excess relative to the analyte, so that any analyte present in the defined volume is substantially depleted from the sample” (emphasis added). Similarly, independent claims 23 and 26 require “the analyte binding partner being present in an amount sufficient to substantially deplete the analyte from a sample” (emphasis added). As further explained on page 14, lines 17-22, of the instant specification, “our theoretical estimates indicate that at least about 60% of the analyte will be captured by a high affinity binding partner having a $K_A > 10^{10}$ liter mole⁻¹” (emphasis added).

Ekins et al. cannot anticipate claims 1-4, 13-19, 21 and 23-26 of the present invention since they do not teach every step of the claimed invention. In particular, Ekins et al. have no teaching whatsoever of a binding assay, which “substantially deplete[s] the analyte from a sample.” To the contrary, in Ekins et al., “only an insignificant proportion of any analyte present in the liquid sample becomes bound to the binding agent” (claim 1, emphasis added). On page 3, lines 28-35, Ekins et al. teach that “insignificant proportion of the analyte is ... generally less than 10%, usually less than 5% and for optimum results only 1 or 2% or less” (emphasis added). These figures are significantly lower than “at least about 60%” of analyte depletion recommended by the instant invention. Therefore, Etkins et al. cannot anticipate independent claims 1, 23 and 26. Claims 2-4, 13-19, 21, 24 and 25 depend directly or indirectly from claims 1, 23 and 26 and are not anticipated by Etkins et al. for at least the same reasons.

Ekins et al. cannot make the present invention obvious. Not only do Ekins et al. have no teaching of an assay which relies on substantially depleting the analyte from a sample (as

discussed above), but they also teach away from the present invention by requiring the opposite limitation of “only an insignificant fraction (generally less than 10%, usually less than 5%) of the analyte ... [to be] bound” (page 4, lines 12-17) (emphasis added). Moreover, Etkins et al. themselves differentiate their approach from a method relying on essentially total sequestration of all analyte. Etkins et al. state (page 4, lines 1-7, emphasis added) that an assay, which relies on a large amount of binding agent and essentially total sequestration of all analyte fails to recognise [sic] the advance achieved by the present invention, which instead relies on a different analytical principle ... which thus requires only a very low proportion of the total analyte molecules present to be sequestered from the sample.

Therefore, in view of the teaching of Etkins et al., one would not have been motivated to arrive at claims 1, 23 and 26 of the present invention. In light of the forgoing, applicants respectfully submit that Etkins et al. cannot make claims 1, 23 and 26 obvious. Claims 2-4, 13-19, 21, 24 and 25 depend directly or indirectly from claims 1, 23 and 26 and are not obvious for at least the same reasons.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claims 5-10 are rejected as being unpatentable over Etkins et al. (EP 304,202), in view of Ullman et al. (US Patent 5,512,659). Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Etkins et al. (EP 304,202), in view of Waggoner et al. (US Patent 5,368,486). Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Etkins et al. (EP 304,202), in view of Waggoner et al. (US Patent 5,368,486), and further in view of Lee et al. (US Patent 5,453,505). Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Etkins et al. (EP 304,202), in view of Northrup et al. (US Patent 5,639,423). Applicants respectfully traverse these rejections.

As discussed above, Etkins et al. cannot make the base claim 1 obvious, because they teach away from the binding assay of the present application, which “substantially deplete[s] the analyte from a sample.” Claims 5-10, 11, 12 and 20 depend directly or indirectly from claim 1 and cannot be made obvious by Etkins et al. for at least the same reasons.

Ullman et al., Waggoner et al., Lee et al. and Northrup et al. cannot remedy the defect of Etkins et al., and are not relied upon by the Examiner for such. Ullman et al., Waggoner et al., Lee et al. and Northrup et al. have no teaching whatsoever of a binding assay utilizing a plurality

of sorbent zones containing analyte binding partner, let alone a binding assay, which requires an excess of the analyte binding partner "relative to the analyte, so that any analyte present ... is substantially depleted from the sample." Therefore, none of the cited references, either alone or in combination, can motivate one skilled in the art to arrive at claims 5-10, 11, 12 and 20. The rejection is improper and should be withdrawn.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Fullerton, California, telephone number 714/773-6969 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,

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